

# PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>RLL-298WO</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/4-16)	
International application No. <b>PCT/B 03/04873</b>	International filing date (day/month/year) <b>31.10.2003</b>	Priority date (day/month/year) <b>31.10.2002</b>
International Patent Classification (IPC) or both national classification and IPC <b>A61K9/00</b>		
Applicant <b>RANBAXY LABORATORIES LIMITED</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of    sheets.

3. This report contains indications relating to the following items:
 

I    ☒ Basis of the opinion

II   ☐ Priority

III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

IV   ☐ Lack of unity of invention

V    ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI   ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand  <b>20.05.2004</b>	Date of completion of this report  <b>16.12.2004</b>
Name and mailing address of the international preliminary examining authority:  <div style="display: flex; align-items: center;"> <div>             European Patent Office              D-80298 Munich              Tel. +49 89 2399 - 0 Tx: 523656 epmu d              Fax: +49 89 2399 - 4465           </div> </div>	Authorized Officer  <b>Giménez Miralles, J</b>  Telephone No. +49 89 2399-8655



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/IB 03/04873**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-6 as originally filed

**Claims, Numbers**

1-21 as originally filed

**Drawings, Sheets**

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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EXAMINATION REPORT - SEPARATE SHEET**

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International application No: PCT/IB 03/04873

**Re Item V**

1. The relevant prior art documents are referred to as D1 to D8 as in the order of appearance in the International Search Report (ISR).
2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Article 33(1) PCT):

- (N) The subject-matter of claims 1-21 is not novel as anticipated by the prior art (Article 33(2) PCT).

D1 discloses an amorphous form of potassium losartan and pharmaceutical compositions containing it. This takes away the novelty of present independent claims 1 and 4.

D2 to D4 disclose crystallization of potassium losartan (form I). First, the potassium salt is synthesized: the free acid form is treated with KOH and concentrated under vacuum prior to crystallization; concentration under vacuum of the reaction mixture must render an amorphous form of the potassium salt; thus an amorphous form is implicitly disclosed in D2 to D4. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The same reasoning applies in view of D5 to D7, because the step of concentration of a solution or reaction mixture of the potassium salt under vacuum prior to crystallization implies the obtention of an amorphous form as an intermediate form. Thus, the amorphous form is implicitly anticipated. This takes away the novelty of present independent claims 1 and 4, as well as independent claim 7.

The mere spectroscopic characterization of a product or material which has been previously (explicitly or implicitly) disclosed does not establish novelty. Furthermore, the parametric definition by reference to the figures in claims 2, 3, 5, 6, 20 and 21 is not allowable, because it results in lack of clarity (Art. 6 PCT).

- (IS) The subject-matter of claims 1-21 is not considered to involve an inventive step (Article 33(3) PCT) (see above).

Further, the following consideration is brought to the applicant's attention:

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Selecting spray-drying or freeze-drying instead of vacuum concentration for obtention of the amorphous form would be an obvious alternative for the skilled person (see e.g. D8). No inventive step can be acknowledged for such subject-matter.

- (IA) The subject-matter of claims 1-21 is considered to be industrially applicable (Article 33(4) PCT. The possibility of industrial application is beyond any doubt.